

**REMARKS**

The claims have been amended to clarify the claimed invention to place the application in condition for allowance at the time of the next Official Action.

The amendment is not believed to require further search and/or consideration, and, thus, consideration and entry of the amendment is respectfully requested.

**Status of the Claims**

Claims 44-57 and 59-63 are amended to clarify the ester as including a sterol ester, as described, for example, in Figures 2-6 and Examples 1-4. Additionally, the optional steps from claims 50-54 and 61 have been removed, as well as the smoothing and cereal addition step from claim 55.

New claims 64-68 and 70 recite the optional steps removed from claims 50-54 and 61, respectively.

New claim 69 includes the smoothing step of claim 55.

Claims 44-70 remain pending.

No new matter has been added.

**Claim Rejections-35 USC §103**

Claims 44-50 and 58-63 were rejected under 35 U.S.C. §103(a) as being unpatentable over BOYER EP 1212945 (BOYER). This rejection is respectfully traversed for the reasons below.

The objective of the claimed invention.

The claimed invention concerns a method for the preparation in a production line of a dairy product comprising a introducing by continuous injection, via the production line, of at least one sterol ester and/or stanol ester at a given temperature  $T_1$  higher than or equal to the melting temperature of the ester, and ranging from 35 to 80°C, into a dairy composition having a given temperature  $T_2$ , at least equal to  $T_1$  corresponding to a milk-based initial composition, containing milk proteins and without thickener or emulsifier, in order to obtain a mixture. The introduction of the sterol ester and/or stanol ester is carried out before the mixture is homogenized.

In the prior art, the incorporation of a sterol and/or stanol ester into a milk composition is carried out in (i) a batch process and (ii) with a stabilizer, essentially a thickener, and with an emulsifier.

Therefore, one of the advantages of the claimed invention is the ability to incorporate a sterol ester and/or a stanol ester into a milk composition without using a batch process but in a continuous injection (i.e. production line).

Another advantage of the claimed invention lies in the fact that the incorporation of the sterol ester and/or stanol ester is carried out without emulsifier.

BOYER

BOYER discloses a process of incorporating cholesterol-lowering agents into dairy-based beverages.

In particular, a melted stanol ester at a temperature of 60°C is incorporated into a milk stabilizer mixture heated at a temperature of 62.8°C. The resultant mixture is then blended in a mixer, and homogenized at a pressure of 137-172 bars and pasteurized at a temperature of 87.8°C for 2 minutes.

The Position of the Official Action

The position of the Official Action was that claims 44-50 and 58-63 are unpatentable over BOYER.

The process of BOYER is only intended for fresh dairy products. BOYER describes only one dairy-based beverage, which is prepared by a batch process and the composition requires a stabilizer (as in page 5 line 25-30 or Example 1) and an emulsifier (see table 1).

Although it must be recognized that paragraph 6 and 14 state that stabilizers could be optional ingredients, as indicated in the Official Action, these statements are general statements in order to encompass a plurality of process covered by the BOYER.

Looking at the definition of the problem to solve by EP1212945 in paragraph 4, it can be read: *"incorporating stanol ester into dairy beverages with lower fat levels, especially*

*reduced fat/fat free milks [such as 2% milk of example 1 and 2 or 1% milk of example] is problematic. Once the dietary ingredient has been introduced into milk formulation and process must be controlled in such a manner as to keep the dietary ingredient in suspension throughout a 60 day shelf life."* (Comment Added.)

The solution to this problem is described in paragraph 7: *"the cholesterol lowering agent is dispersed throughout the milk matrix. The milk matrix contains among other things, milk and a cholesterol lowering agent."* (Emphasis Added.)

Thus, the milk matrix of BOYER does not merely consist of a dairy composition (milk) and a cholesterol-lowering agent. Instead, additional "other things" are always necessary.

Looking at examples 1, 2 and 3, the stanol ester (cholesterol lowering agent) is added into skimmed milk and then stabilizers and salts are introduced.

In paragraph 20, the stanol ester is added to the milk mixed with stabilizers.

In paragraph 18, a stabilizer is also used.

Therefore, the "other things" necessary, i.e., in addition to the dairy composition (milk) and the cholesterol-lowering agent, in the examples 1 to 3 and paragraph 20, are stabilizers.

Thus, if one reviews paragraph 6 again, which states that stabilizers could be optional ingredients, removing the

stabilizers would give a milk matrix without the "other things", which would be contrary to paragraph 7.

In conclusion, as shown by all the examples and paragraph 7, the compositions of BOYER always contain at least a stabilizer, which is a "thickener" in the present specification and also in certain cases, an emulsifier. The claimed process, however, includes neither a stabilizer nor a emulsifier.

If stabilizers were really optional ingredients, one skilled in the art would have had some difficulty understanding the meaning of "other things" and why stabilizers are always used by BOYER.

To reinforce this statement, a look at the European procedure is very instructive, as BOYER is deemed to be withdrawn because the European Examiner considers that increased stabilization has been demonstrated for dairy-based beverages comprising 0.2-2% stanol ester and 0.1-0.5% of a stabilizer.

No increased stabilization has been demonstrated for stanol ester containing dairy-based beverages containing 0.01-0.05% emulsifier in the absence of stabilizers. The European Examiner concluded that claim 1 reformulated to contain stabilizer as defined in claim 3 in an amount of 0.01-0.5% (as defined in claim 2) would be allowed.

Further, Applicant respectfully disagree with the position presented in the Official Action concerning paragraph 13 of BOYER, as this paragraph confirms that a stabilizer or a

stabilizing agent is essential and must be used: *"Additionally, it may be possible to eliminate the need for stabilizers by substituting stanol with other selected fatty acids for a stabilizing agent".* (Emphasis Added.)

Thus, when no stabilizer is used, a stabilizing agent ("other things") must be used, demonstrating thus that the stabilizer cannot be optional in the composition.

Concerning now the process in itself, Applicant again respectfully disagrees with the position presented in the Official Action, which stated that paragraph 11 describes the process as including an in-line mixer that includes pasteurization.

Paragraph 11 describes the variety of techniques known to those having skilled in the art to disperse stanol ester into milk.

Several techniques are disclosed, the one cited in the Official Action and describing that a stanol ester can be injected into the milk in front of an inline high shear mixer and circulated in the milk being one example among the six given.

Therefore, it cannot be stated that the process of BOYER is described in paragraph 11. The process is only described in paragraph 20 and in the examples.

Further, the applicant notes that the Official Action agrees with applicant in that the process of BOYER is not disclosed as a continuous process.

However, the applicant respectfully disagrees that it is known in the art to process milk products in a continuous manner, as asserted in the Official Action. This position appears to rely on "official notice".

Applicant would be grateful if Examiner could provide a document confirming this assertion.

Therefore, the main differences between the process of BOYER and the claimed invention are:

- the need for a stabilizer in BOYER, and
- the process is carried out in a batch process in BOYER.

In addition, as sated in the Official Action, BOYER does not mention yoghurt, and, as already affirmed in the previous reply to the first Official Action, it is well known that carrageenan is not compatible with fermented dairy product processes. Indeed, carrageenan and other polymers cause a flocculation of proteins in acidic medium.

Moreover, the quality of a dairy product is determined by its texture and it will be appreciated by the consumer only by its proteic array. The use of carrageenan does not allow the structuring of such an array, and, therefore, carrageenan does not lead to a product with acceptable qualities.

In conclusion, the process according to the claimed invention using neither thickener nor emulsifier, and being

carried out by continuous injection and not in a batch process, is non-obvious.

Therefore, withdrawal of the rejection is respectfully requested.

#### **Claim Rejections-35 USC §112**

Claims 44-63 were rejected under 35 U.S.C. §112, second paragraph, for being indefinite. This rejection is respectfully traversed for the reasons below.

The claims were rejected for not being clear as to whether sterol is an ester or not. The claims have been amended to clarify this feature, e.g., consistent with the Figures 2-6 and Examples 1-4.

Claims 50-54 and 61 were rejected for including an optional step. These optional steps are now separately recited in new claims 64-68 and 70, respectively.

Therefore, the claims are definite, and withdrawal of the rejection is respectfully requested.

#### **Conclusion**

In view of the amendment to the claims and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.



Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

Please charge the fee of \$364.00 for the extra independent and dependent claims added in which the fees are being paid online simultaneously herewith by credit card.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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